Applicant: Kimihiro Mabuchi et al. Attorney's Docket No.: 19461-0004US1 / 547267

Serial No.: 10/582,052

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REMARKS

This reply is filed in response to the final Office action dated September 3, 2010. Claims 1-7 and 17 are presented for examination. Claims 8-16 remain withdrawn.

Initially, Applicants would like to thank the Examiner for the telephone interview with their counsel held on November 29, 2010. During the interview, the Examiner agreed that "the ratio of a hydrophilic polymer and a hydrophobic polymer in the outer surface" disclosed in the sole reference cited in the final Office action, Saruhashi, has a meaning different from the phrase "the content of a hydrophilic polymer in the outer surface" recited in claim 1 and should be calculated based on the method described in Applicants' reply filed on July 15, 2010. More specifically, the Examiner agreed that, given that Saruhashi discloses the ratio of a hydrophilic polymer and a hydrophobic polymer in the outer surface is 5-25%, the content of Saruhashi's hydrophilic polymer in the outer surface in a membrane is at most 20%, which is less than 25-50 mass% recited in claim 1. In other words, claim 1 is not anticipated by Saruhashi. At the end of the interview, the Examiner indicated that, after a reply to the final Office action is filed to summarize the discussion during the interview in writing, he will withdraw the sole anticipation rejection based on Saruhashi in the final Office action and will reopen prosecution. In addition, the Examiner encouraged Applicants to present nonobviousness arguments in the reply to expedite prosecution. Other points discussed during the interview are summarized below.

Claims 1-7 are rejected under 35 U.S.C. §102(b) as anticipated by Saruhashi et al., JP 2000-254222 ("Saruhashi"). As noted above and in Applicants' July 15, 2010 reply, Saruhashi does not disclose that the content of its hydrophilic polymer in the outer surface of a hollow fiber membrane is 25 to 50 mass %, as required by claim 1. Thus, claim 1 is not anticipated by Saruhashi.

In addition, claim 1 would not have been obvious over Saruhashi. The present application refers to Saruhashi as "Patent Literature 10" and states that this reference discloses a method of <u>decreasing</u> the ratio of the hydrophilic polymer to the hydrophobic polymer on the outer surfaces of hollow fiber membranes to <u>5-25%</u> (i.e., having a content of the hydrophilic polymer of <u>4.7-20 mass%</u>) to inhibit the infiltration of endotoxins into the blood contact sides of the membranes. *See* paragraphs [0013]-[0014] of the specification and paragraphs [0003], [0007], and [0010] of Saruhashi. However, the present application teaches that the method

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disclosed in Saruhashi suffers from at least the following problem: the membranes disclosed in Saruhashi have lower compatibility with the physiological salt solution and therefore lower priming capacity (*i.e.*, an air purging capacity for wetting the membranes). See paragraph [0014] of the specification.

On the other hand, the inventors named in the present application discovered that, by controlling the content of the hydrophilic polymer in the outer surface of a membrane to 25-50 mass%, the above problem encountered by the membranes disclosed in Saruhashi can be overcome. Specifically, the present application teaches in paragraph [0033] that

"When the content of the hydrophilic polymer of the outer surface of the membrane is less than 25 mass %, the content of the hydrophilic polymer in a whole of the membrane, particularly on the inner surface of the membrane becomes too low, so that the compatibility of the membrane with the blood or the permeability thereof tends to lower. In case of the dried membrane, the priming capacity may become insufficient."

The present application also teaches in paragraph [0035] that

"When the content of the hydrophilic polymer on the outer surface of the membrane exceeds 50 mass %, endotoxins in the dialysing fluid may more and more possibly infiltrate into the blood contact side of the membrane, which may induce side effects such as fevers, etc. Further, the hollow fiber membranes stick to one another due to the hydrophilic polymer present on the outer surfaces of the membranes while the membranes are being dried, and consequently, the module-fabricating workability may become poor."

Thus, the present application teaches that controlling the content of the hydrophilic polymer in the outer surface of a membrane to 25-50 mass% can both improve the priming capacity of the membrane and inhibit the infiltration of endotoxins into the blood contact side of the membrane, which was not achieved by the membranes disclosed in Saruhashi.

Further, the membrane recited in claim 1 has the following characteristic: the difference between the maximum and the minimum out of the maximum values of UV absorbance of the extracted solutions from the hollow fiber membranes is not larger than 0.05. The present application teaches in paragraphs [0046] and [0047] that

"[b]y doing so, variation in the contents of poly(vinylpyrrolidone) in the outer surfaces of the hollow fiber membranes along the lengthwise direction of the bundle of hollow fiber membranes, which would give adverse influence on the sticking of the membranes, can be inhibited. ... the problem of the partial sticking

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of the hollow fiber membranes, which would be caused in the lengthwise direction of the bundle and which has never been solved so far as described above, can be solved."

Saruhashi does not disclose or suggest membranes having the above characteristic.

Thus, for at least the reasons set forth above, claim 1 would not have been obvious over Saruhashi.

Applicants submit that this application is now in condition for allowance and request favorable action.

Any circumstance in which Applicants have: (a) addressed certain comments of the Examiner does not mean that Applicants concede other comments of the Examiner; and (b) made arguments for the patentability of some claims does not mean that there are not other good reasons for the patentability of those claims and other claims.

Please apply any other charges to deposit account 06-1050, referencing Attorney's Docket No. 19461-0004US1.

Respectfully submitted,

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